**UNITED STATES DISTRICT COURT**

**WESTERN DISTRICT OF LOUISIANA**

**MONROE DIVISION**

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| **THOMAS CALLAWAY AND THELMA CALLAWAY** | * | **CIVIL ACTION NO. 11-00193** |
| **VERSUS** | * | **JUDGE ROBERT G. JAMES** |
| **AMERICAN MEDICAL SYSTEMS, INC.** | * | **MAG. JUDGE KAREN L. HAYES** |

**REPORT AND RECOMMENDATION**

Before the undersigned Magistrate Judge, on reference from the District Court, is a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6) filed by Defendant American Medical Systems, Inc. ("Defendant") (Doc. # 13). The motion is unopposed. For reasons stated below, it is recommended that Plaintiffs be given 30 days to amend their complaint, and in the absence of an appropriate amendment, that Defendant's motion to dismiss be **GRANTED**, dismissing, with prejudice, plaintiffs' complaint in its entirety.

**PROCEDURAL AND FACTUAL BACKGROUND**

On February 1, 2011, Thomas and Thelma Callaway ("Plaintiffs") filed a complaint alleging that a penile prosthesis implanted in Thomas following surgery for prostate cancer has proven to be defective. Doc. # 1. The complaint claims that the device, an AMS 700 MS Series Penile Prosthesis, has not functioned properly since the surgery in that Thomas is unable to obtain an erection. The complaint further alleges that the prosthesis was covered by a lifetime warranty, and that, despite Plaintiffs' compliance with Defendant's warranty procedures, the warranty remains dishonored. *Id.*

Plaintiffs claim that the damages they have sustained were caused by the "fault, negligence, and/or strict liability" of the Defendant, and that Defendant is liable on several theories of recovery under the Louisiana Products Liability Act ("LPLA"), La. Rev. Stat. Ann. § 9:2800.51, *et seq*. *See* Doc. # 1, ¶ 9. These theories include: (1) unreasonably dangerous design, manufacture, marketing, and/or construction; (2) failure to use alternative designs; 3) unreasonably dangerous construction and composition; (4) failure to provide adequate warnings and instructions; and (5) failure to conform to express and/or implied warranties.[1] *Id.* Plaintiffs seek damages for past, present and future medical expenses, benefits, loss of enjoyment of life, mental anguish, emotional distress, disability, disfigurement, and mental and physical pain and suffering. *Id.* at ¶¶ 10-11. They also claim Defendant is liable to Thelma for past, present, and future loss of consortium, service, love, affection and society, and mental anguish. *Id.* at ¶ 12.

On September 30, 2011, Defendant filed a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6), on the grounds that: (1) Plaintiffs' product liability claims are expressly preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a); and (2) even assuming the claims are not preempted, Plaintiffs' complaint fails to set forth even the most basic facts that would fairly place Defendant on notice as to the nature of the claims being asserted. Doc. # 13. Plaintiffs have not filed a response to the motion.

**LAW AND ANALYSIS**

When considering a motion to dismiss, the Court must accept as true the well-pleaded

[1] It should be noted that some of these theories, including "failure to conform to implied warranties," are not cognizable in Louisiana. *See* La. Rev. Stat. Ann. § 9:2800.52 ("This Chapter establishes the exclusive theories of liability for manufacturers for damages caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter.").

factual allegations in the complaint, and construe them in the light most favorable to the plaintiff. *Johnson v. Dallas Indep. Sch. Dist.*, 38 F.3d 198, 205 (5th Cir. 1994), *cert. denied*, 514 U.S. 1017 (1995). "The district court may not dismiss a complaint under Rule 12(b)(6) unless it appears beyond a doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). "Nevertheless, minimal requirements [of pleadings] are not tantamount to non-existent requirements. The threshold may be low, but it is real — and it is the plaintiff's burden to take the step which brings his case safely into the next phase of the litigation." *Gooley v. Mobile Oil Corp.*, 851 F.2d 513, 514 (1st Cir. 1998). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted).

**I. MDA Preemption**

Defendant first argues that any claim Plaintiffs could conceivably assert under the LPLA would be preempted by federal law. Doc. # 13-1, pp. 8-15. It should first be noted that federal law categorizes medical devices into three groups: Class I, Class II, and Class III. *See* 21 U.S.C. § 360c(a). The penile prosthesis that is the subject of this lawsuit is a Class III medical device;[2] these devices are subject to the highest degree of federal oversight. Before a Class III medical device can be sold, it must receive an approval or clearance from the Food and Drug Administration ("FDA"). § 360c(a)(1)(C).

The Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act render invalid any requirement of state law applicable to a device that is "different from, or

[2] *See Malbroux v. Jancuska*, No. 11-421, 2011 WL 3816104, at *2, (W.D. La. Aug. 29, 2011).

in addition to" the requirements of the FDA and that "relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device." 21 U.S.C. § 360k(a). This express preemption clause operates to safeguard the FDA's comprehensive analysis concerning both Pre-market Approval process ("PMA")-approved and Product Development Protocol ("PDP")-completed devices from modification or interference through the various tort law principles of the fifty states.[3]

In *Riegel v. Medtronic*, 552 U.S. 312 (2008), the Supreme Court found that state-law claims of strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, sale, and manufacture were all preempted by Section 360k of the MDA because the device at issue was a PMA-approved, Class III medical device. *Id.* at 330. In so doing, the Court utilized a two-pronged analysis, considering: 1) whether the FDA had established federal requirements applicable to the device at issue; and 2) whether the state-law claims were premised on state requirements that were "different from, or in addition to" the federal requirements, and that related to safety and effectiveness. *Id.* at 321-22. The undersigned will employ the same analysis in this case.

A. *Riegel*'s First Prong

In *Riegel*, the Supreme Court found that the PMA process itself imposes device-specific, federal "requirements" for purposes of preemption analysis. *Id.* at 1006-07. The Supreme Court noted that the PMA process is "specific to individual devices" because "the FDA may grant pre-market approval only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Id.* at 1007. PDP completion is equivalent to PMA approval, and if a device is PMA-approved or has received a declaration of PDP completion, then the first prong of the

[3] *See Riegel v. Medtronic*, 552 U.S. 312, 321-25 (2008).

preemption analysis is satisfied.[4]

On November 2, 1998, the penile prosthesis at issue received a declaration of PDP completion.[5] The conditions of PDP approval govern AMS's design, manufacturing, and labeling of the device. Therefore, through the PDP process, the FDA has established federal "requirements" that apply specifically to the penile prosthesis at issue in this case. Hence, the first prong of the *Riegel* preemption analysis is satisfied.

B. *Riegel*'s Second Prong

As for the second prong, Defendant maintains that Plaintiffs' allegations impose state law requirements that are different from, or in addition to, the federal requirements, and that are related to safety and effectiveness. *See Riegel*, 552 U.S. at 321-25. Defendant argues that Plaintiffs' claim that the device is defective necessarily means that it is not reasonably safe and effective as designed, manufactured and labeled, which would be an assertion directly contrary to the FDA's declaration of PDP completion. Doc. # 13-1, pp. 13-14. In other words, "the only way that Plaintiffs could prevail in this case would be for a jury to decide that the Penile Prosthesis is not reasonably safe and effective or that it is inappropriately labeled — an outcome totally at odds with the FDA's conclusion on the exact same issue." *Id.* at p. 14 (emphasis omitted).

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[4] *See* 21 U.S.C. § 360e(f)(1) (explaining that with respect to Class III devices requiring PMA-approval, "such device shall be considered as having [pre-market approval] if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6)." *See also Clement v. Kaiser Foundation Health Plan, Inc.*, No. 04-704, 2004 WL 3049753, at *4 (C.D. Cal. Dec. 17, 2004) ("The Court is inclined to agree that the PDP process is as rigorous, at least for purposes of preemption, as the PMA process."); *Cowen v. American Medical Systems, Inc.*, No. 05-10307, 2006 WL 3542704, at *1 (E.D. Mich. Dec. 7, 2006) (same).

[5] *See* FDA Declaration of PDP Completion, Exh. 2 to Mot. to Dismiss, *Malbroux v. Jancuska*, No. 11-421, 2011 WL 3816104 (W.D. La. Aug. 29, 2011), ECF No. 10-3.

Defendant also states that "[w]hile the Complaint is impermissibly conclusory and vague, it is nevertheless possible to appreciate that all conceivable claims are preempted." *Id.* at p. 13. The undersigned disagrees with this assessment; the nature of Plaintiffs' complaint makes it impossible to conduct a meaningful analysis of the preemption issue. In the complaint, Plaintiffs matter-of-factly state that the penile prosthesis is defective, and they then list several theories under which Defendant is allegedly liable for their damages. Therefore, given the utter lack of any factual allegations in the complaint, the undersigned is unable to determine at this time whether the Plaintiffs' claims are premised on state requirements that are "different from, or in addition to" the federal requirements, and that relate to safety and effectiveness.

**II. Rule 8 Pleading Standards**

Defendant next argues that the complaint should be dismissed for failing to satisfy federal pleading standards. Doc. # 13-1, pp. 15-17. Federal Rule of Civil Procedure 8(a)(2) requires that every pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The purpose of this requirement is to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). The Supreme Court recently revisited the pleading standards, clarifying that:

> [w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.

*Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). Indeed, "Rule 8(a)(2) . . . requires a 'showing,' rather than a blanket assertion, of entitlement to relief[,]" since "[w]ithout some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only 'fair notice' of the nature of the claim, but also 'grounds' on

which the claim rests." *Id.* at 555, n.3 (citing 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1202, pp. 94, 95 (3d ed. 2004).

The Court continued that "something beyond the mere possibility of [a claim] must be alleged" and that "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed [to discovery]." *Id.* at 557-58. Gone are the days when a plaintiff could assert "a wholly conclusory statement of claim" and survive a motion to dismiss simply because his "pleadings left open the possibility that [he] might later establish some set of undisclosed facts to support recovery." *Id.* at 561-62; *see also In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 592 F. Supp. 2d 1147 (D. Minn. 2009).

In this case, the Plaintiffs' complaint clearly falls victim to the above-described malady. It simply recites legal theories of recovery, some of which are precluded by the LPLA, without any further explanation. Doc. # 1, ¶ 9. It fails to allege that AMS is the manufacturer of the penile prosthesis.[6] It fails to describe with any particularity what it is about the device that is "defective" or "unreasonably dangerous."[7] And it is completely silent as to how the undefined defect in the prosthesis is causally related to any injuries.[8] In fact, the complaint alleges no

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[6] *See Stanley v. Wyeth*, 2007-2080 (La. App. 1 Cir. 5/2/08); 991 So. 2d 31, 33, n.2 (to assert a valid LPLA claim, a plaintiff must allege that the defendant is the manufacturer of the product alleged to be defective); *cf. Sherman v. Stryker Corp.*, No. 09–224, 2009 WL 2241664, at *5 (C.D. Cal. Mar. 30, 2009) (failure to allege drug manufacturer produced medication at issue warranted dismissal under *Twombly*).

[7] *See*, *e.g.*, *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (plaintiff's manufacturing defect claim dismissed because, *inter alia*, original and first amended complaints did not specify the manufacturing defect, nor did they specify a causal connection between any specific defect in the manufacturing process and the personal injury).

[8] *See Covert v. Stryker Corp.*, No. 08-447, 2009 WL 2424559, at *15 (M.D.N.C. Aug. 5, 2009) (granting *Twombly* motion after concluding that the complaint failed to allege "any

specific wrongdoing whatsoever on the part of Defendant, other than to conclusorily state that it is liable for Plaintiffs' damages.

In sum, as the claim is currently alleged, it clearly fails to meet the pleading standard established by Rule 8 and *Twombly*. Nevertheless, the Plaintiffs may still be able to allege a non-preempted claim if they remedy the defects in their complaint. Thus, the undersigned recommends that the Plaintiffs be allowed thirty days to amend their complaint to allege a non-preempted claim for relief.

**CONCLUSION**

Based on the foregoing discussion, it is recommended that Defendant's motion to dismiss under Rule 12(b)(6) be **GRANTED**, and that Plaintiffs' claims be **DISMISSED with prejudice**, as they fail to state a claim upon which relief may be granted. **HOWEVER, IT IS FURTHER RECOMMENDED** that the Plaintiffs be given at least thirty (30) days in which to prevent dismissal by amending the complaint to allege a non-preempted claim for relief that would satisfy federal pleading requirements.

Under the provisions of 28 U.S.C. § 636(b)(1)(c) and F.R.C.P. Rule 72(b), the parties have **fourteen (14) days** from service of this Report and Recommendation to file specific, written objections with the Clerk of Court. A party may respond to another party's objections within **fourteen (14) days** after being served with a copy thereof. A courtesy copy of any objection or response or request for extension of time shall be furnished to the District Judge at the time of filing. Timely objections will be considered by the District Judge before he makes a final ruling.

**A PARTY'S FAILURE TO FILE WRITTEN OBJECTIONS TO THE PROPOSED**

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particular non-conclusory link between [the] alleged wrongdoing and [plaintiff's] particular injuries, let alone a causal one").

**FINDINGS, CONCLUSIONS AND RECOMMENDATIONS CONTAINED IN THIS REPORT WITHIN FOURTEEN (14) DAYS FROM THE DATE OF ITS SERVICE SHALL BAR AN AGGRIEVED PARTY, EXCEPT ON GROUNDS OF PLAIN ERROR, FROM ATTACKING ON APPEAL THE UNOBJECTED-TO PROPOSED FACTUAL FINDINGS AND LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT JUDGE.**

THUS DONE AND SIGNED at Monroe, Louisiana, this 8th day of December, 2011.

KAREN L. HAYES
U. S. MAGISTRATE JUDGE